

## **REMARKS**

The pending Office Action addresses and rejects claims 1-20. Applicants respectfully request reconsideration based on the remarks submitted herewith.

### ***Claim Amendments***

Applicants amend claim 9 to fix the typographical error noted by the Examiner in the Examiner's most recent rejection. More particularly, the term "fen-icyanide" was replaced with the term "ferricyanide." No new matter is added.

### ***Double Patenting***

Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 6-8, 11, 12, 14-20, and 27-30 of U.S. Patent No. 6,638,415 of Applicants in view of U.S. Patent No. 5,437,999 of Diebold et al. Applicants agree to submit a Terminal Disclaimer with respect to the term of the '415 patent in the event that the Examiner maintains this rejection once patentable subject matter has been found.

### ***Claim Objections***

The Examiner objects to claim 9 because of an informality. In particular, the Examiner points out that a typographical error was present in previous versions of the claims. Applicants have fixed this typographical error by way of amendment in this response, thereby obviating the objection.

### ***Rejections Pursuant to 35 U.S.C. § 102(b)***

The Examiner rejects claims 1-9 and 17-20 pursuant to 35 U.S.C. § 102(b) as being anticipated by International Publication No. WO 97/18464 ("the WO '464 patent"). In making the rejection, the Examiner notes that the WO '464 patent is in the same family as foreign priority document PCT/AU96/00724 (in fact the WO '464 patent is PCT/AU96/00724, and thus will be referred to as "the WO '464 patent" as well), and then also notes that the present application claims

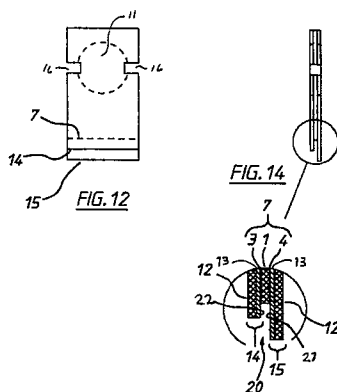
priority back to the WO '464 patent via a number of continuations and continuations-in-part. It is the Examiner's position that each of the continuations and continuations-in-part in the chain leading from the WO '464 patent to the present application do not disclose all of the claimed subject matter in the present application, and that to the extent that claimed subject matter is present in the WO '464 patent but not present in each of the continuations and continuations-in-part in the chain between the WO '464 patent and the present application, that such disclosures in the WO '464 patent qualify as prior art.

More particularly, the Examiner argues that the subject matter of a "device for detecting a presence or an absence of a redox reactive analyte" (claim 1) where the analyte can include an "antioxidant" (claim 8) or an "oxidant" (claim 10) is not disclosed in any application prior to U.S. Application Serial No. 09/615,691, which issued as U.S. Patent No. 6,638,415 ("the '415 patent"). The present application is a continuation of the '415 patent. There were two U.S. applications prior to the '415 patent, as discussed in further detail below. The Examiner also argues that a device containing a "quantity of reagent sufficient for only a single test" (claim 1) is not disclosed in any application prior to the '415 patent. Still further, the Examiner argues that disclosures related to the mediators of claims 9-11, the buffers of claims 12 and 13, and the heating elements of claims 14-16 were not disclosed in any application prior to the '415 patent.

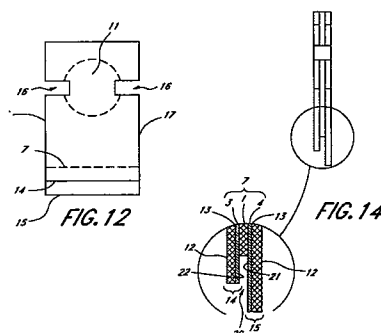
The present application claims foreign priority to two separate PCT applications. As explained above, it claims priority to PCT/AU96/00724 (i.e., the WO '464 patent). It also claims priority to PCT/AU99/00152, which is also International Publication No. WO 99/46585 ("the WO '585 patent") and will be discussed in further detail below with respect to the Examiner's rejection of claims 14-16 as being obvious over the WO '464 patent in view of the WO '585 patent. The WO '464 patent actually claims priority to a provisional Australian application PN 6619. The first U.S. patent to claim priority to the WO '464 patent in this family is U.S. Patent No. 6,179,979 ("the '979 patent"). From the '979 patent, a continuation was filed that resulted in U.S. Patent No. 6,174,420 ("the '420 patent"). The specifications of the WO '464 patent, the '979 patent, and the '420 patent are nearly identical. The only discernable differences between the three patents are the first paragraph under the heading "BACKGROUND ART" (which explains the priority claim and

related patents of each patent and thus is, not surprisingly, a bit different in each patent) and the headings in one section of each patent (in the WO '464 patent and the '420 patent a heading is labeled "DISCLOSURE OF THE INVENTION" while in the '979 patent the corresponding heading is labeled "SUMMARY OF THE INVENTION"). Otherwise, it appears that these specifications are identical. For example, the Examiner argues that the WO '464 patent "discloses a device for detecting the presence or absence of a redox reactive analyte in an aqueous sample (e.g. glucose in blood)" at page 7, lines 17-24 and in Figures 12 and 14. Both the '979 patent and the '420 patent have the exact same Figures 12 and 14 as the WO '464 patent and each of the three contains the exact same disclosure as found at page 7, lines 17-24 of the WO '464 patent (found at Col. 4, lines 34-44 of the '979 patent and at Col. 4, lines 26-36 of the '420 patent):

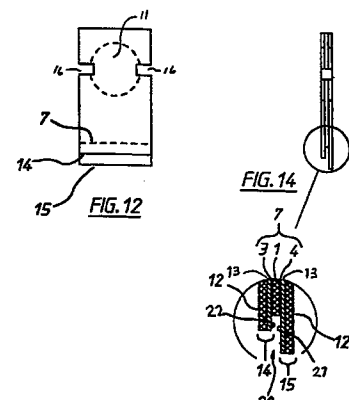
There is thus produced a cell as shown in Figures 12, 13 or 14. The cell comprises a first electrode consisting of PET layer 12, a palladium layer 13, an adhesive layer 3, a PET sheet 1, a second adhesive layer 4, a second electrode comprising palladium layer 13, and a PET layer 12. Sheet 1 defines a cylindrical cell 11 having a thickness in the cell axial direction corresponding to the thickness of the Melinex® PET sheet layer 1 together with the thickness of adhesive layers 3 and 4. The cell has circular palladium end walls. Access to the cell is provided at the side edge of the cell where notches 16 intersect cell 11.



FIGS. 12 and 14  
 of the WO'464 patent



FIGS. 12 and 14  
 of the '979 patent

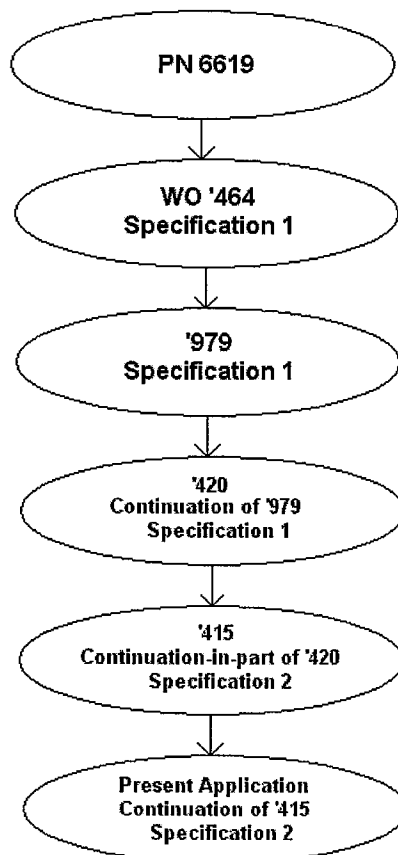


FIGS. 12 and 14  
 of the '420 patent

Similarly, each of the other portions of the WO '464 patent cited by the Examiner as anticipating the present application are also disclosed in the '979 patent and the '420 patent.

Turning again to the chain of priority, from the '420 patent a continuation-in-part was filed that resulted in the '415 patent. As stated above, the present application is a continuation of the '415 patent. The specifications of the '415 patent and the present application are nearly identical, with the only discernable difference being the opening paragraph under the heading "RELATED APPLICATIONS" (which explains the priority claim and related patents of each patent and thus it is, not surprisingly, a bit different in each patent). The specification of the WO '464 patent, the '979 patent, and the '420 patent ("Specification 1") is not identical to the specification of the '415 patent and the present application ("Specification 2").

A chart of the priority chain is illustrated below:



It is the Examiner's position that the '420 patent and the '979 patent do not disclose all of the claimed subject matter in the present application. It is also the Examiner's position that the WO '464 patent anticipates the present application, i.e. that it does disclose all of the claimed subject matter of claims 1-9 and 17-20. These two positions are completely contradictory. As is discussed and illustrated above, and as can be seen in the specifications of each of the WO '464 patent, the '420 patent, and the '979 patent, the specifications are nearly identical. Accordingly, it cannot be possible for the '420 and the '979 patent to lack a sufficient disclosure to allow the present application to claim priority back to the WO '464 patent, and for the WO '464 patent to contain a sufficient disclosure to anticipate the present application. It has to be either one or the other. Either the specification of the WO '464 patent, the '420 patent, and the '979 patent, i.e. Specification 1, includes disclosures that anticipate the claimed subject matter, in which case the present application can properly claim priority back to the WO '464 patent and it cannot be an anticipatory reference, or Specification 1 does not include disclosures that cover the claimed subject matter, in which case there can be no rejection for anticipation pursuant to 35 U.S.C. § 102(b). Whether claim 1 can claim priority back to the WO '464 patent or claim 1 is not anticipated by the WO '464 patent, either way claim 1 represents allowable subject matter.

Accordingly, Applicants request allowance of claim 1, as well as claims 2-9 and 17-20 which depend therefrom.

***Rejections Pursuant to 35 U.S.C. § 103(a)***

Claims 10 and 11

The Examiner rejects claims 10 and 11 pursuant to 35 U.S.C. § 103(a) as being obvious over the WO '464 patent in view of either U.S. Patent No. 6,042,714 of Lin et al. ("Lin") or U.S. Patent No. 5,938,917 of Mulchandani ("Mulchandani"). In particular, the Examiner relies on both Lin and Mulchandani to teach reagents that are useful for the monitoring of oxidant species. Independent claim 1, from which both claims 10 and 11 depend, is directed to a device for detecting a presence or an absence of a redox reactive analyte in an aqueous sample, where the device includes an electrochemical cell that has: a sensing chamber; two electrodes mounted on opposite sides of an

electrically resistive material; a first aperture that defines a sidewall of the cell, a first electrode area, and a second electrode area; a second aperture for admitting a sample into the sensing chamber; and a reagent disposed on a support that is only in an amount sufficient for a single test. Further, the device of claim 1 is configured such that the reagent is capable of undergoing a redox reaction directly with the analyte to generate an electrical signal indicative of the presence or absence of the analyte and the electrochemical cell is designed to be disposed of after use in a single experiment. Lin, meanwhile, is directed to a chemical sensor for measuring a concentration of a  $H_2O_2$  precursor in a liquid that includes a transducer for conducting an electric current and a composition deposited on a surface of the transducer such that the composition includes a catalyst that is a urea oxidase or a cholesterol oxidase for the  $H_2O_2$  production reaction and a mixed-valence compound having a specific formula. Mulchandani is directed to a method for selectively detecting a peroxide analyte in a sample by applying an electric potential to the sample when the sample is in contact with an electrode. Both Lin and Mulchandani fail to teach or even suggest many of the recitations of independent claim 1, including an electrochemical cell designed to be disposed of after use in a single experiment having: one or more walls; a sensing chamber; electrodes mounted on opposite sides of electrically resistive material; first and second apertures as recited; and a reagent only in an amount sufficient for a single test. At least because the WO '464 patent is either not a proper prior art reference or does not teach each and every limitation of claim 1, and further because neither Lin nor Mulchandani remedy all of the deficiencies of the WO '464 patent, this rejection cannot be maintained.

Accordingly, Applicants request allowance of claims 10 and 11, which both depend from an allowable base claim.

Claims 8, 9, 12, and 13

The Examiner rejects claims 8, 9, 12, and 13 pursuant to 35 U.S.C. § 103(a) as being obvious over the WO '464 patent in view of U.S. Patent No. 5,120,420 of Nankai et al. ("Nankai"). In particular, the Examiner relies on Nankai to teach the use of a phosphate buffer for the reagent layer and that an electrochemical sensor with ferricyanide as the reagent can be utilized as a detector

for antioxidants such as ascorbic and uric acid. Independent claim 1, from which claims 8, 9, 12, and 13 each depend, is directed to a device for detecting a presence or an absence of a redox reactive analyte in an aqueous sample, where the device includes an electrochemical cell that has: a sensing chamber; two electrodes mounted on opposite sides of an electrically resistive material; a first aperture that defines a sidewall of the cell, a first electrode area, and a second electrode area; a second aperture for admitting a sample into the sensing chamber; and a reagent disposed on a support that is only in an amount sufficient for a single test. Further, the device of claim 1 is configured such that the reagent is capable of undergoing a redox reaction directly with the analyte to generate an electrical signal indicative of the presence or absence of the analyte and the electrochemical cell is designed to be disposed of after use in a single experiment. Nankai, meanwhile, is directed to a biosensor for determining a substrate concentration in a sample solution that includes: a base plate with an electrode system that includes at least an electrode for measurement and a counter electrode, such that the electrode system can determine a substrate concentration in a sample solution; and a reaction layer having a space that is provided with a port for introducing the sample solution into the space and a port for discharging the gas in the space. Nankai fails to teach or even suggest many of the recitations of independent claim 1, including an electrochemical cell designed to be disposed of after use in a single experiment having: one or more walls; electrodes mounted on opposite sides of electrically resistive material; first and second apertures as recited; and a reagent only in an amount sufficient for a single test. At least because the WO '464 patent is either not a proper prior art reference or does not teach each and every limitation of claim 1, and further because Nankai fails to remedy all of the deficiencies of the WO '464 patent, this rejection cannot be maintained.

Accordingly, Applicants request allowance of claims 8, 9, 12, and 13, which each depend from an allowable base claim.

#### Claims 14 and 15

The Examiner rejects claims 14 and 15 pursuant to 35 U.S.C. § 103(a) as being obvious over the WO '464 patent in view of U.S. Patent No. 5,342,498 of Graves et al. ("Graves"). In particular,

the Examiner relies on Graves to teach the addition of a heating element that allows the temperature of the sensor and analyte to be precisely controlled. Independent claim 1, from which both claims 14 and 15 depend, is directed to a device for detecting a presence or an absence of a redox reactive analyte in an aqueous sample, where the device includes an electrochemical cell that has: a sensing chamber; two electrodes mounted on opposite sides of an electrically resistive material; a first aperture that defines a sidewall of the cell, a first electrode area, and a second electrode area; a second aperture for admitting a sample into the sensing chamber; and a reagent disposed on a support that is only in an amount sufficient for a single test. Further, the device of claim 1 is configured such that the reagent is capable of undergoing a redox reaction directly with the analyte to generate an electrical signal indicative of the presence or absence of the analyte and the electrochemical cell is designed to be disposed of after use in a single experiment. Graves, meanwhile, is directed to an electronic wiring board having a substrate with a temperature sensor and at least one analyte sensor on the same side of the substrate, and a heater located on another side of the substrate to provide heat in response to a sensed temperature, which in turn allows for the temperature of a region of the board to be controlled within a narrow distribution of temperatures. Graves fails to teach or even suggest many of the recitations of independent claim 1, including an electrochemical cell designed to be disposed of after use in a single experiment having: one or more walls; a sensing chamber; electrodes mounted on opposite sides of electrically resistive material; first and second apertures as recited; and a reagent only in an amount sufficient for a single test. At least because the WO '464 patent is either not a proper prior art reference or does not teach each and every limitation of claim 1, and further because Graves fails to remedy all of the deficiencies of the WO '464 patent, this rejection cannot be maintained.

Accordingly, Applicants request allowance of claims 14 and 15, which both depend from an allowable base claim.

#### Claims 14-16

The Examiner rejects claims 14-16 pursuant to 35 U.S.C. § 103(a) as being obvious over the WO '464 patent in view of International Publication No. WO 99/46585 (i.e., the WO '585 patent).



Applicants note that to the extent that the WO '464 patent is not proper prior art because the present application claims priority thereto, the WO '585 patent is also not proper prior art because the priority date of the present application is earlier than the filing date of the WO '585 patent. Further, because the present application claims priority back to the WO '585 patent, the WO '585 patent is also not proper prior art. More specifically, as discussed above, the present application is a continuation of the '415 patent. Further, the '415 patent is a continuation-in-part of PCT/AU99/00152, which is the WO '585 patent. At least because the WO '464 patent is either not a proper prior art reference or does not teach each and every limitation of claim 1, and further because the WO '585 patent is not a proper prior art reference, this rejection cannot be maintained.

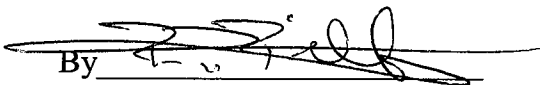
Accordingly, Applicants request allowance of claims 14-16, which each depend from an allowable base claim.

### ***Conclusion***

In view of the reasons set forth above, each of the presently pending claims in this application is believed to be in condition for allowance, and reconsideration is respectfully requested. The Examiner is urged to telephone the undersigned Attorney for Applicants in the event that such communication is deemed to expedite prosecution of this matter.

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Respectfully submitted,

By 

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